

REMARKS

Applicants respectfully request reconsideration of the present application in view of the following commentary.

I. Status of the Claims

No claim amendments are made in this response. Claims 1-16, 18, 25-26, 45-46, 62-63, 68 and 82-99 were previously cancelled. Claims 17, 19-24, 27-44, 47-61, 64-67 and 69-81 are pending.

II. Rejection of Claims under 35 U.S.C. §103(a)

Claims 17, 19-24, 27-44, 47-61, 64-67 and 69-81 are rejected under 35 U.S.C. §103(a) for alleged obviousness over U.S. Patent No. 6,241,969 to Saidi et al. (“Saidi”) in view of U.S. Patent Publication No. US 2002/0065256 A1 by Karlsson et al. (“Karlsson”). Applicants respectfully traverse the rejection.

The Examiner asserts that Saidi teaches corticosteroids including fluticasone and that examples 1-4 teach sterilizing diluted corticosteroid compositions by passing them through a 0.22 micron sterile filter. Applicants respectfully disagree.

First, even if combined, both the cited references fail to teach that a dispersion containing particles of fluticasone can pass through a 0.2 μm filter. With a more detailed read of Examples 1-4 of Saidi, one skilled in the art would understand that Saidi does not teach or describe passing a *dispersion* of fluticasone particles through a 0.2 μm filter, as recited by the present claims. Rather, Saidi describes passing *a solution* of beclomethasone dipropionate, budesonide, or triamcinolone acetonide through a 0.22 micron filter. The claims require that the fluticasone be present in a particle form, and more specifically, that the form is one of crystalline, amorphous, or semi-crystalline. In other words, the particles of the dispersion have a shape and size. Saidi requires that the active agents are *dissolved* to form a solution before passing the composition

through a 0.22 micron filter. Specifically, Saidi suggests adding co-solvents to his composition to ensure that the corticosteroid is dissolved. *See* col. 5, lines 15-18.

Karlsson does not cure the deficiency of Saidi. The secondary reference, Karlsson, expressly states that the active agent is *not* passed through a 0.2 micron filter, only the other components of the composition (which has been consistently argued by the Applicant in prior responses). Therefore, even if there was a reason to combine the references, neither Saidi nor Karlsson discloses that a dispersion containing fluticasone particles can pass through a 0.2 μm filter.

Second, Karlsson teaches away from filtering the corticosteroid. As noted above, Karlsson discloses excluding the active agent from the solution that is passed through a 0.2 micron filter. In contrast, Saidi teaches that the active agent be in a solution form in order to pass through a filter. Accordingly, one would not have arrived at the claimed invention, that is, passing particles of fluticasone through a filter, when reading the disclosures of Saidi in conjunction with Karlsson.

Third, the Examiner asserts that Karlsson is cited for the alleged teaching of a surface stabilizer, which is lacking from Saidi. The purpose of the surface stabilizer in Karlsson is “[t]o obtain an efficient dispersion of the glucocorticosteroid particles in the suspension” (page 3, paragraph [0034]). Saidi describes dissolving the active agents to form a stable solution and then passing the solution through a filter. As such, there is no need to “obtain an efficient dispersion.” Accordingly, no surface stabilizer is necessary for the solution containing the active agent in Saidi. Therefore, one of ordinary skill in the art would have no reason to take the surface stabilizer of Karlsson and put it into the solution of Saidi. A reason to combine the references is lacking. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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